REMARKS

Any fees that may be due in connection with the filing of this paper or with this application may be charged to Deposit Account No. 06-1050. If a Petition for Extension of time is needed, this paper is to be considered such Petition.

Claims 1-3, 12 and 15-18 are pending in this application. Claims 13 and 14 are cancelled herein without prejudice or disclaimer. Claims 1-3 are amended herein to clarify the nature of the claimed subject matter. Claims 15-18 are added herein. Basis for the amended and added claims can be found in the specification, for example, at page 6, lines 21-27; at page 21, lines 22-25; at page 22, line 4 to page 23, line 19; at page 30, line 25 to page 31, line 1; and in Example 3 beginning at page 52. No new matter is added.

INFORMATION DISCLOSURE STATEMENTS

The Office Action alleges that the Information Disclosure Statements filed December 24, 2003, and May 20, 2003, fail to comply with the provisions of 37 CFR §§1.97, 1.98 and MPEP §609 because English translations were not provided for some of the non-English language patents. Specifically, the Examiner states that Japanese Patent No. JP63503007, submitted with the Information Disclosure Statement filed December 24, 2003, and listed in the accompanying Form PTO-1449 as Item Q, has not been considered as to the merits because an English translation allegedly has not been provided. The Examiner further alleges that in the Information Disclosure Statement filed May 20, 2003, German Patent Nos. DE19618032, DE19731479, DE4431174 and DE4438630 (listed in the Form PTO-1449 as items HN, HO, IA and IB, respectively) have not been considered because English translations of these documents are not provided.

As a preliminary matter, Applicant respectfully notes that the Examiner appears inadvertently to refer to the Information Disclosure Statement filed November 20, 2003, as having been filed on May 20, 2003. Applicant respectfully seeks correction if this assumption is in error. Further, as described below, it respectfully is submitted that the Information Disclosure Statements filed December 24, 2003, and November 20, 2003, are in compliance with 37 CFR §§1.97, 1.98 and MPEP §609.

With respect to the Information Disclosure Statement filed December 24, 2003, the English language Derwent abstract for Japanese patent JP63503007 is listed as item AE on the form PTO-1449 accompanying the Information Disclosure Statement. Item AE also is described in the third paragraph (pages 1-2) of the Information Disclosure Statement filed

December 24, 2003. The Information Disclosure Statement filed December 24, 2003, and the accompanying document AE are accessible as an Image File Wrapper corresponding to the above-captioned application in the public PAIR database of the USPTO website (hereinafter, "PAIR").

With respect to the Information Disclosure Statement filed November 20, 2003, Applicant respectfully submits that the German patents listed as Items HN, HO, IA and IB were provided with English language Derwent abstracts (items LZ, MF, MB and MA, respectively). This Information Disclosure Statement also is available as an Image File Wrapper in PAIR, and a copy of the Express Mail receipt and returned date stamped postcard submitted with the Information Disclosure Statement filed November 20, 2003, is attached hereto. In addition, the aforementioned German patents and corresponding Derwent abstracts were provided in an Information Disclosure Statement filed June 4, 2002, in connection with U.S. Application Serial No. 09/880,988 (hereinafter, the '988 application), which is relied upon for an earlier filing date in accordance with 35 U.S.C. §120. These documents were initialed and considered by the Examiner during prosecution of the '988 application. Copies of sheets 10 and 11 of the initialed forms PTO-1449 accompanying the Information Disclosure Statement filed June 4, 2002, in connection with the '988 application, are included with this response.

Because English language Derwent abstracts have been provided in connection with the Japanese and German patents that form the basis of this objection, and further because English language Derwent abstracts, English language equivalents, or Certified English language translations have been provided for all foreign language documents provided with the Information Disclosure Statements filed December 24, 2003, and November 20, 2003, Applicant respectfully submits that these Information Disclosure Statements are in accordance with the requirements of 37 C.F.R. §1.98, as amended effective March 16, 1992. Therefore, no further explanation of the listed items is necessary. Accordingly, Applicant respectfully requests that the Examiner make the aforementioned Information Disclosure Statements and documents cited therein of record in the file history of the above-captioned application.

THE REJECTION OF CLAIMS 1, 3 and 14 UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claim 1 is rejected under 35 U.S.C. §112, second paragraph, as indefinite because there allegedly is no clear recitation of a nexus between the preamble, which recites that the method is drawn to identifying nucleotides in a "plurality" of target nucleic acid molecules, and the first step of the method, which recites a "target nucleic acid." Dependent Claims 3 and 14 also are rejected as indefinite in their recitation of mass-matched "nucleotide" because Claim 1, from which they depend, recites "mass-matched nucleotides."

This rejection is rendered moot with respect to Claim 14, which is cancelled herein. With respect to the remaining claims, the objections are addressed by amending Claim 1 to consistently recite "target nucleic acid molecules" throughout the claim, and by amending Claim 13 to recite "mass-matched nucleotides."

THE REJECTION OF CLAIMS 1-3 and 12-14 UNDER 35 U.S.C. §102(b)

Claims 1-3 and 12-14 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 5,547,835, to Köster. The Examiner alleges that the Köster patent discloses a mass spectrometric method of identifying bases in target nucleic acids that includes Sanger sequencing by primer extension using modified nucleotides, including mass-matched nucleotides, and measuring a "mass shift," *i.e.*, a difference between the mass of an incorporated nucleotide and a reference mass. This rejection is respectfully traversed. Reconsideration of this rejection respectfully is requested in view of the amendments herein and the following remarks. This rejection is rendered moot with respect to Claims 13 and 14, which are cancelled herein.

RELEVANT LAW

Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. In re Spada, 15 USPQ2d 1655 (Fed. Cir, 1990), In re Bond, 15 USPQ 1566 (Fed. Cir. 1990), Soundscriber Corp. v. U.S., 360 F.2d 954, 148 USPQ 298, 301, adopted 149 USPQ 640 (Ct. Cl.) 1966. See, also, Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913,1920 (Fed. Cir.), cert. denied, 110 S.Ct. 154 (1989). "[A]ll limitations in the claims must be found in the reference, since the claims measure the invention." In re Lang, 644 F.2d 856, 862, 209 USPQ 288, 293 (CCPA 1981). Moreover it is incumbent on Examiner to identify wherein each and every facet of the claimed invention is disclosed in the reference. Lindemann Maschinen-fabrik Gmbh v. American Hoist and Derrick Co., 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984). Further, the reference must

describe the invention as claimed sufficiently to have placed a person of ordinary skill in the art in possession of the invention. An inherent property has to flow naturally from what is taught in a reference In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981).

"Rejections under 35 U.S.C. §102 are proper only when the claimed subject matter is identically disclosed or described in the "'prior art'" . . .the [r]eference must clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings in the cited references. Such picking and choosing may be entirely proper when making a rejection of a 103, obviousness rejection, where the applicant must be afforded an opportunity to rebut with objective evidence any inference of obviousness which may arise from the similarity of the subject matter which he claims to the prior art, but it has no place in the making of a 102, anticipation rejection." (Emphasis in original). In re Arkey, Eardly, and Long, 455 F.2d 586, 172 USPQ 524 (CCPA, 1972).

THE CLAIMS

Independent Claim 1 as amended herein is directed to a method for identifying nucleotides at one or more base positions in a plurality of target nucleic acid molecules that are polymorphic or mutant sequence variants of a gene or portion thereof by synthesizing extension products of the target nucleic acid molecules in the presence of chain terminating nucleotides and mass-matched nucleotides; determining the mass of each extension product; and calculating a mass shift corresponding to each nucleotide from a period for the mass of each extension product. Dependent Claim 2 specifies that the mass-matched nucleotides are identical, dependent Claim 3 specifies particular mass-matched nucleotide compounds and dependent Claim 12 specifies that the chain terminating nucleotides are mass-matched.

New dependent Claim 15 is directed to the method of claim 1, where the target nucleic acid molecules are polymorphic sequence variants. New Claim 16 specifies that the difference in sequence between the variants of Claim 15 is a single nucleotide polymorphism. New dependent Claim 17 is directed to the method of claim 1, where the target nucleic acid molecules are mutant sequence variants. New Claim 18 specifies that the difference in sequence between the variants of Claim 17 is an insertion or a deletion.

Thus, all the rejected claims and new claims are directed to a method for identifying nucleotides at one or more base positions in a plurality of target nucleic acid molecules,

which includes a step of calculating a mass shift based on a period for the mass of each extension product synthesized from the target molecules.

ANALYSIS

The Köster patent discloses methods of sequencing nucleic acids by mass spectrometry. The Köster patent discloses that extension products of target nucleic acids, obtained by Sanger sequencing, can be analyzed by mass spectrometry of the nested, base-specific, chain-terminated product fragments of the target nucleic acids. Köster discloses that in some embodiments, mass-modified nucleic acid sequencing primers, chain-elongating and/or terminating nucleoside triphosphates, or mass-modified fragments containing "tag sequences" can be used to obtain better resolution of the base-specifically terminated fragments.

In the Köster patent, the terminal nucleotide of an extension product is identified by subtracting the absolute mass of the product from that of the preceding extension product. Unlike the instant methods, there is no disclosure of sequencing (*i.e.*, identifying nucleotides at one or more base positions of a target nucleic acid molecule) by calculating a mass shift from a period. As discussed below, the calculation of a mass shift from a period for the mass of each extension product, as recited in the instant Claim 1 and claims dependent thereon, is different from a step as disclosed in Koster that relies on the difference between two absolute mass measurements.

As the instant application describes, a prevailing problem prior to the instant application was the ambiguity associated with mass spectrometric measurement of the absolute mass of a nucleic acid molecule and, in the case of multiplexing, with measuring differences between the absolute masses of more than one nucleic acid molecule being analyzed simultaneously (*see* specification for example, at page 29, line 15 to page 30, line 18). Although in sequencing applications, the terminal nucleotide of an extension product is identified by subtracting the mass of the product from the preceding extension product, as the cited passages describe, the mass measurement of both extension products are absolute and can fall anywhere on the mass axis, especially when the target nucleic acid products are large, of identical length, or of closely related sequence such as polymorphisms, especially single nucleic acid polymorphisms, and mutations of a gene or portion thereof. This creates an ambiguity in identifying the terminal nucleotide, making the result unreliable.

In the instant methods, the ambiguity associated with measuring the absolute masses of the extension products from sequencing target nucleic acids is reduced by creating a periodic mass distribution (*i.e.*, an absolute regular periodicity) and calculating a mass shift for each extension product from its corresponding periodic reference mass (*see, e.g.*, specification at page 18, line 27 to page 19, line 9). The mass shift calculated according to the step recited in instant Claim 1 and claims dependent thereon is based on the greater reliability of a mass difference (*i.e.*, mass shift) that is measured relative to a predetermined periodic reference mass than a mass difference that is the subtraction product of two absolute masses on a mass axis. As the specification describes (*see, e.g.*, page 6, lines 21-27), the mass shift as recited in the instant claims is engineered by selecting, depending on the particular application and the resolving power of the mass measuring instrument, suitable nucleotide analogs and/or chain terminating nucleotides and/or primers that creates a distinct, unambiguously resolvable mass for each extension product based on its terminal base position, base identity, and overall sequence. The value of the mass shift is dependent on the particular application (sequencing, diagnosis, assessing differences in base composition), and the value is determined by the judicious selection of primers, nucleotide analogs, and/or chain terminating nucleotides, as well as a consideration of the resolution power of the mass measuring instrument. Thus, for example:

(1) If the application is Sanger sequencing of a single target nucleic acid molecule, the values of mass shift should be unique for extension products containing each of the four chain terminating nucleotides (ddA, ddT, ddC, ddG), and the mass measuring instrument should have a resolution that is smaller than the lowest value of mass shift. The value of the mass shift, $M_{diff}[n] = M_{obs}[n] - M_{PR}[n]$; where

$M_{PR}[n] = (M_{primer} + Ml_{ight}) + (n - 1) P_{base}$;

$M_{obs}[n]$ is the observed peak;

where:

n is the base position;

$M_{PR}[n]$ is the nth periodic reference mass;

M_{primer} is the mass of the primer;

M_{light} is the mass of the lightest nucleotide chain terminator.

(2) If the application is simultaneous Sanger sequencing of more than one target nucleic acid molecule (multiplexing), the value of the mass shift for extension products containing

each of the four chain terminating nucleotides should be unique, as discussed above. In addition, however, the separation between extension products of the same length and/or mass that arise from different target nucleic acid molecules should be such that its value is greater than that of the maximum mass shift, *i.e.*, the difference between the mass of the heaviest chain terminating nucleotide (M_{heavy}) and the lightest chain terminating nucleotide (M_{light}). Thus, each target nucleic acid molecule is sequenced using a primer and/or mass-matched nucleotide of distinct mass, so that the mass shifts corresponding to extension products from each of the target nucleic acid molecules are unique.

The mass shift calculated from a period for the mass of each extension product permits unambiguous identification of nucleotides in a plurality of target nucleic acids, even when their sequences are closely related as in polymorphisms or mutations of the same gene or portion thereof. Köster does not disclose any such step of calculating a mass shift from a period for the mass of each extension product. Because Köster does not disclose any methods that include calculating a mass shift from a period, Köster does not anticipate the instantly claimed method Claim 1, nor any claims depedent thereon, including newly added Claims 15-18.

THE REJECTION OF CLAIMS 1-3 UNDER 35 U.S.C. §101

Claims 1-3 are rejected under 35 U.S.C. §101 on grounds of statutory double patenting. It is alleged that these claims are identical to the claims 5, 7 and 8 of prior issued patent U.S. Patent No. 6,660,229. This rejection is obviated by amending the instant claims to specify that the plurality of target nucleic acids analyzed by the methods are polymorphic or mutant sequence variants of a gene or portion thereof.

THE REJECTION OF CLAIMS 12-14 ON GROUNDS OF OBVIOUSNESS-TYPE DOUBLE-PATENTING

A. **Claim 12** is rejected on grounds of non-statutory obviousness-type double patenting as allegedly being unpatentable over Claims 9 and 10 of U.S. Patent No. 6,660,229. Specifically, it is alleged that Claim 12 extends the right of exclusivity of issued Claims 9 and 10 of the parent because the subject matter of Claims 9 and 10 allegedly are "species" of the general method set forth in Claim 12. Reconsideration of this rejection respectfully is requested in light of the amendments herein and the following remarks.

RELEVANT LAW

Obvious-type double patenting occurs when the difference between a first-patented invention and a later claimed invention involves only an unpatentable difference, such that

grant of the second patent would extend the right of exclusivity conferred by the first patent. *See, e.g., General Foods Corp. v. Studiengesellschaft Kohle mbH*, 23 USPQ2d 1839, 1845 (Fed. Cir. 1992). Analysis for obvious-type double patenting involves a comparison of the claims at issue "with what invention is *claimed* in the earlier patent, paying careful attention to the rules of claim interpretation to determine what invention a claim *defines* and not looking to the claim for anything that happens to be mentioned in it as though it were a prior art reference." *Id.* (emphasis in original); *see, also, Ortho Pharm. Corp. v. Smith*, 22 USPQ2d 1119, 1125 (Fed. Cir. 1992) ("It is the claims, not the specification that defines an invention [citation] . . . [a]nd it is the claims that are compared when assessing double patenting."). Thus, an obviousness-type double patenting rejection is based on the claims and not on the disclosure of a patent.

The comparison between claims in an obviousness-type double patenting inquiry requires the use of a fundamental rule of claim construction, that the invention is defined by the claim taken as a whole – every claim limitation (or each step) being material to the description of the invention. *Ortho Pharm. Corp.*, 22 USPQ2d at 1125. Thus, it is inappropriate to base an obviousness-type double patenting rejection on the disclosure of a patent, even when such disclosure is found in the claims. Only the claims are considered in determining whether obviousness-type double patenting exists and they are not used as disclosure but are interpreted based on the rules of claim construction.

Obviousness-type double-patenting has not been found when claims at issue do not embrace the prior patent compounds and/or the claims in the prior patent do not suggest any modification that would have produced the claimed compounds in the patent or application at issue. *See, e.g., Id.* In *Ortho*, obvious-type double patenting was not found in an instance in which the claims in the patent at suit were directed to compounds that did not encompass, structurally, the compounds claimed in the prior patents, and the claims in the prior patents did not suggest a modification (based upon the principles of claims interpretation) of their compounds to produce compounds claimed in the patent at suit.

ANALYSIS

Applicant respectfully submits that the basis for the rejection is improper. Obviousness-type double-patenting is analyzed using the principles of claim interpretation to assess whether a grant of a second patent would extend the right of exclusivity afforded by the first patent (i.e., the issued parent, U.S. Patent No. 6,660,229). The question to be asked

is whether the claim(s) of the second patent, if issued (in this case, Claim 12), would encompass the subject matter of the issued claims of the first patent (Claims 9 and 10) and, if not, is it an obvious modification of the issued claims of the first patent.

In this case, Claim 12 is directed to a different method from issued Claims 9 and 10 of the parent. Claim 12 is directed to a method using mass-matched nucleotides to identify one or more nucleotides in a plurality of target nucleic acid molecules that are polymorphic or mutant sequence variants. Issued Claims 9 and 10 of U.S. Patent No. 6,660,229, are directed to methods using pair-matched nucleotides and a hairpin primer to identify nucleotides of a target nucleic acid molecule. It respectfully is submitted that instant Claim 12, directed to identifying nucleotides in polymorphic or mutant sequence variants, does not encompass the subject matter of issued Claims 9 and 10, directed to identifying nucleotides of a target nucleic acid,.

Further, the method of Claim 12 is not an obvious modification of the methods claimed in issued patent U.S. Patent No. 6,660,229. None of the issued claims include a limitation directed to identifying nucleotides in a plurality of target nucleic acids that are sequence variants of a target nucleic acid molecule. Applicant therefore respectfully submits that as between instant Claim 12 and issued Claims 9 and 10 of U.S. Patent No. 6,660,229, obviousness-type double-patenting does not exist

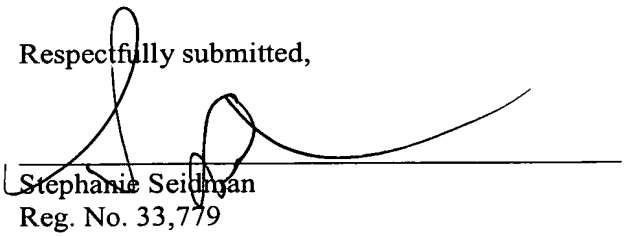
B. **Claims 13 and 14** are rejected on grounds of non-statutory obviousness-type double patenting as allegedly being unpatentable over Claims 1 and 4 of U.S. Patent No. 6,660,229, in view of Köster. Specifically, it is alleged that Claims 13 and 14 differ from issued Claims 1 and 4 in that a plurality of target nucleic acid molecules are assessed in a single experiment (Claim 13) or different mass-matched nucleotides are used (Claim 14), and Köster allegedly teaches these deficiencies.

Without addressing the merits of this rejection, Claims 13 and 14 are cancelled herein, thereby rendering this rejection moot

* * *

In view of the above, examination of the application on the merits and allowance is respectfully requested.

Respectfully submitted,



Stephanie Seidman
Reg. No. 33,779

Attorney Docket No. 17120-011002 / 2408B
Address all correspondence to:
Stephanie Seidman
Fish & Richardson P.C.
12390 El Camino Real
San Diego, California 92130
Telephone: (858) 678-5070
Facsimile: (202) 626-7796
email: seidman@fr.com

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APPLICANT: CANTOR *et al.*
APPL. NO: 10/645,816 FILED: AUGUST 20, 2003
FOR: **USE OF NUCLEOTIDE ANALOGS IN THE ANALYSIS OF OLIGONUCLEOTIDE MIXTURES AND IN HIGHLY MULTIPLEXED NUCLEIC ACID SEQUENCING**

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PLEASE STAMP HERE (THANK YOU):

FORM PTO-1449 (Modified)	ATTY. DOCKET NO. 25491-2408	SERIAL NO. 09/880,988
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	APPLICANT CANTOR et al.	
	FILING DATE June 13, 2001	GROUP 1634

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB CLASS	Translation Yes	Translation No
AC	GV	0 3 6 0 6 7 6	03/28/90	EP				X*
	GW	0 5 4 3 5 5 0	05/26/93	EP A1				
	GX	0 5 9 3 7 8 9	04/27/94	EP (A1)				
	GY	0 5 9 6 2 0 5	05/11/94	EP				
	GZ	0 6 8 3 2 3 4	11/22/95	EP				
	HA	0 7 7 1 0 1 9	05/02/97	EP				
	HB	0 8 2 8 8 5 5	12/15/99	EP				
	HC	1 9 6 1 7 0 11	04/27/96	DE				X+
	HD	1 9 6 1 8 0 32	05/04/96	DE				X+
	HE	1 9 6 2 8 1 78	07/12/96	DE				X*
	HF	1 9 7 3 1 4 79	08/06/98	DE A1				X*
	HG	1 9 7 5 4 9 78	12/11/97	DE				X+
	HH	2 0 1 7 1 0 5	03/20/79	UK				
	HI	2 2 1 5 3 9 9	08/28/90	JP				X*
	HJ	2 2 3 3 6 5 4	01/16/91	GB				
	HK	2 2 6 0 8 1 1	04/28/93	GB (A)				
	HL	2 3 1 2 7 8 2	11/05/97	UK				
	HM	2 3 3 2 2 7 3	06/16/99	UK				
	HN	2 5 9 7 2 6 0	05/02/91	FR			X	
	HO	2 7 4 9 6 6 2	11/06/96	FR				X*
	HP	3 2 2 1 6 8 1	12/08/83	DE			X	
↓	HQ	4 1 7 8 3 5 9	06/25/92	JP A				X*
AC	HR	4 4 3 1 1 7 4	03/07/96	DE (A1)				X*

EXAMINER Arun kr. Chakrabarti | DATE CONSIDERED 9/23/02

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Title: **USE OF NUCLEOTIDE ANALOGS IN THE ANALYSIS OF OLIGONUCLEOTIDE MIXTURES AND IN HIGHLY MULTIPLEXED NUCLEIC ACID SEQUENCING**

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FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUB CLASS	Translation Yes	Translation No
AC	HS	4	4	3	8	6	3	0	05/02/96	DE (A1)				X*
	HT	6	3	2	3	0	0	86	09/26/88	JP				X*
	HU	8	5	0	2	9	0	7	07/04/85	PCT				
	HV	8	9	0	3	4	3	2	04/20/89	PCT				
	HW	8	9	0	6	7	0	0	07/27/89	PCT				
	HX	8	9	1	2	6	2	4	12/28/89	PCT				
	HY	8	9	1	2	6	9	4	12/28/89	PCT				
	HZ	9	0	0	1	5	6	4	02/22/90	PCT				
	IA	9	1	1	1	5	3	3	01/10/91	PCT				
	IB	9	1	1	5	6	0	0	10/17/91	PCT				
	IC	9	2	0	5	2	8	7	04/02/92	PCT				
	ID	9	3	0	9	6	6	8	05/27/93	PCT				
	IE	9	3	1	5	4	0	7	08/05/93	PCT				
	IF	9	3	2	3	5	6	3	11/25/93	PCT				
	IG	9	3	2	4	8	3	4	12/09/93	PCT				
	IH	9	4	1	6	1	0	1	07/21/94	PCT				
	II	9	4	2	0	9	7	8	09/15/94	PCT				
	IJ	9	4	2	1	8	2	2	09/29/94	PCT				
	IK	9	4	2	7	7	1	9	11/16/95	PCT				
	IL	9	4	2	8	4	1	8	12/08/94	PCT				
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AC	IO	9	5	1	3	3	8	1	05/18/95	PCT				

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